

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

BRUESEWITZ, et al.,

Plaintiffs,

v.

WYETH, INC.,

Defendant.

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Civil Action

NO. 05-5994

FILED

AUG 24 2007

MICHAEL J. DOLAN
CLERK

MEMORANDUM

Baylson, J.

August 24, 2007

I. Introduction

Presently before the Court are Defendant's Motions for Summary Judgment (Doc. Nos. 22, 73, 88) in this products liability suit, on the grounds that: (1) the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"), 42 U.S.C. § 300aa-1 *et seq.*, preempts tort claims for the allegedly defective design of a vaccine under § 300aa-22(b)(1) of the Act; (2) § 22(c) bars Plaintiffs' failure-to-warn claim; and (3) as to any claims not preempted by the Vaccine Act, there are no genuine issues of fact for trial. For the reasons set forth below, the Court finds Counts I and III fo the Amended Complaint are preempted by the Vaccine Act, and that Plaintiffs have failed to raise any genuine issue of material fact as to Counts II and IV. Accordingly, Defendant's Motions will be GRANTED.

II. Background

A. Procedural Background

On April 3, 1995, Plaintiffs filed a petition in the United States Court of Federal Claims seeking compensation as provided by the Vaccine Act. 42 U.S.C. § 300aa-1 *et seq.* On February

14, 2003, Plaintiffs rejected the judgment of the Vaccine Court. These proceedings followed. Plaintiffs initially filed their Complaint in the Philadelphia County Court of Common Pleas in October, 2005. Defendant removed the case to this Court based on diversity of citizenship, and filed a first Motion for Summary Judgment (Doc. No. 22). Plaintiffs filed their Response (Doc. No. 29), and Defendants timely replied (Doc. No. 32).

This defense motion was based on Wyeth's contention that Plaintiffs' claims were preempted. The Court considered this motion as premature since little, if any, discovery had taken place and eventually denied this motion without prejudice, by Order dated February 22, 2007.

The parties engaged in extensive discovery, and the Court held several unrecorded pretrial conferences. The Court expressed some confusion over the nature of Plaintiffs' claims, and on January 23, 2007, required Plaintiffs to serve a contention statement listing Plaintiffs' claims in more detail. An Amended Statement of Contentions was filed by Plaintiffs on February 1, 2007 (Doc. No. 55).

The Court again noted, in its Memorandum and Order of February 22, 2007, that although Plaintiffs were making a claim of negligence for a manufacturing defect, Plaintiffs had not yet specifically alleged a claim for strict liability based on manufacturing defect, and held that such a claim would not be encompassed within the negligence cause of action asserted in the original Complaint. Although Plaintiffs had not sought leave to file an amended complaint, the Court suggested Plaintiffs move to amend their Complaint if they wished to proceed to trial on a strict liability claim relating to manufacturing. Plaintiffs did file a Motion for Leave to file a First Amended Complaint on March 7, 2007 (Doc. No. 67). On March 9, 2007, the Court entered an

Order requiring briefing on Plaintiffs' Motion for Leave to File an Amended Complaint, discussing the impact of the claims presented in the Motion to Amend (and specifically the new claim based on strict liability for manufacturing defect) in the context of the preemption issues already briefed. As noted in the Order, Plaintiffs' counsel had advised the Court that Plaintiffs would not require any additional discovery if the amendment was allowed, but Defendant's counsel reserved the right to pose contention interrogatories. The Court directed any fact discovery should be completed by April 5, 2007.

The Court designated briefs previously filed on certain issues to be considered as supporting Defendant's legal position that Plaintiffs' claims were preempted, or alternatively, that Plaintiffs had failed to raise a genuine issue of material fact requiring a trial.

By Memorandum and Order dated April 18, 2007, the Court reviewed the procedural history of the case, and although noting Wyeth's objection to the Amended Complaint, particularly the claim of strict liability for manufacturing defect, the Court stated it would allow Plaintiffs to add a count for strict liability for manufacturing defect "to give Plaintiffs an opportunity to show that there is factual support to show a genuine issue for trial on the claim that there was a manufacturing defect in the specific lot or lots of vaccine administered to the Plaintiffs' minor." The Amended Complaint became the operative statement of Plaintiffs' claims.

The Court again gave leave for additional discovery, and entered a schedule for the completion of the briefing on the pending defense Motions for Summary Judgment. Defendant asserts that all four Counts of the Amended Complaint are preempted by the Vaccine Act, or in the alternative, that Plaintiff has failed to raise any questions of material fact, warranting

summary judgment pursuant to Fed. R. Civ. P. 56.

B. Factual Background

Pursuant to the Court's standard practice, Defendant filed Statements of Undisputed Facts (Doc. Nos. 22, 88) to which Plaintiffs responded (Doc. Nos. 29, 95). From Defendant's statements of fact and Plaintiffs' counter-statements, the Court establishes the following facts which are not in dispute:

Minor Plaintiff, Hannah Bruesewitz, received her third diphtheria-pertussis¹-tetanus ("DPT") vaccine in April, 1992. (Def's First Statement of Undisputed Facts ¶ 1; see also Pl's Resp. to Def's First Statement of Undisputed Facts ¶ 1.) At the time of this vaccination, the Advisory Committee on Immunization Practices recommended administration of the DPT vaccine five times, at approximately 2, 4, 6 and 15-18 months, and 4-6 years of age. (Id. ¶ 2.) Born on October 20, 1991, Hannah received the first three doses of the DPT vaccine according to this recommendation. (Id. ¶¶ 3-4.) After her third vaccination, Hannah suffered a seizure, and was subsequently diagnosed with "residual seizure disorder" and "developmental delay." (Id. ¶ 5.)

Defendant's DPT vaccine administered to Hannah (trade name, TRI-IMMUNOL®) contained whole, killed pertussis cells (the "whole-cell" vaccine). (Id. ¶ 6.) The National Health Institute first issued a product license to American Cyanamid Company ("Cyanamid") in 1948 for TRI-IMMUNOL®, which was produced by Lederle Laboratories, an unincorporated division of Cyanamid. (Def's Second Statement of Undisputed Facts ¶¶ 13, 19.) In 1994 American Home Products Corporation ("AHPC") acquired Cyanamid. (Id. ¶ 15.) From 1948 until 1998,

¹ Pertussis is the disease also commonly known as whooping cough.

when AHPC voluntarily discontinued the manufacture of TRI-IMMUNOL®, Cyanamid, and after 1994, AHPC, held a valid product license for TRI-IMMUNOL®. (Id. ¶ 19.)

At the time of Hannah's vaccination, the Food and Drug Administration ("FDA") had already approved Defendant's application for an alternative DPT vaccine (trade name, ACEL-IMUNE®) that contained "an acellular pertussis component." (Def.'s First Statement of Undisputed Facts ¶ 7.) The FDA's approval at that time only allowed Defendant to distribute ACEL-IMUNE® for the fourth and fifth doses in the DPT vaccination series. (Id. ¶ 8.) The FDA approved the first acellular pertussis vaccine for use in the first three doses of the vaccination series on July 31, 1996 (id. ¶¶ 9, 10); ACEL-IMUNE® did not obtain such approval until December 1996 (id. ¶ 11).

C. Allegations in the Amended Complaint

Although the Amended Complaint purports to restate the claims of the original Complaint, the Court regards the Amended Complaint as the operative statement of Plaintiffs' claims. The Amended Complaint proceeds with four counts. Count I alleges Wyeth negligently failed to produce a safer vaccine despite knowledge of the existence and feasibility of such safer alternatives. (Am. Compl. ¶¶ 32-34.) Count II alleges Wyeth negligently failed to warn of the actual dangers associated with the particular batch DPT vaccine administered to Hannah Bruesewitz. (Id. ¶ 35) Count III asserts strict liability for design defect, in that the existence or feasibility of safer alternative designs for the vaccine rendered the vaccine administered to Hannah defective and unreasonably dangerous. (Id. ¶ 36.) Count IV asserts strict liability for manufacturing defect, in that, in addition to the unreasonable danger due to the aforementioned alleged design defect, the particular dose of vaccine administered to Hannah contained a

manufacturing defect that made it “extra-hazardous.” (*Id.* ¶ 37.) Plaintiffs are suing for damages to Hannah Bruesewitz, costs, punitive damages, and other legal or equitable relief the Court deems just and proper. (*Id.* ¶¶ 38-41.)

III. Parties’ Contentions²

A. Defendant

Defendant’s Motions for Summary Judgment claim the Vaccine Act precludes all of Plaintiffs’ claims. As to Count I Defendant contends the negligence allegations in the Complaint must be construed as a design defect claim. According to Defendant, the plain language of the Vaccine Act reflects the intent of Congress to preempt state law claims for design defects. Defendant argues that this is a broad immunity, not subject to case-by-case review in the courts, mandating dismissal of Counts I and III.

Defendant maintains the Vaccine Act also explicitly bars the failure-to-warn claim in Count II. Defendant points out that the Act provides immunity from suit for failure to warn when the suit is based on a failure to warn directly any member of the general public. Wyeth further argues it is entitled to a presumption that the warnings accompanying the vaccine in question were proper as a matter of law, and Plaintiffs cannot produce any evidence to overcome that presumption, entitling it to immunity from suit for failure-to-warn under the Vaccine Act.

As to Count IV, Wyeth first argues Plaintiffs have not actually pleaded a manufacturing defect, but rather a design defect, in that the flaws alleged to exist in the vaccine administered to Hannah represent differences in the reactivity among different batches of the vaccine, inherent in

²Both parties have filed multiple briefs on Defendant’s three summary judgment motions. This summary draws from all the briefs submitted by the parties.

the design of the whole-cell pertussis vaccine. According to Wyeth, allowing Count IV to go forward would, in essence, allow the very case-by-case review of vaccines it claims the Vaccine Act preempts.

Alternatively, Wyeth offers arguments in favor of summary judgment addressing the merits of Plaintiffs' claims. First, Wyeth argues that no genuine issue of material fact exists as to Count I of the Amended Complaint because Wyeth did not act unreasonably as a matter of law in marketing an FDA-approved vaccine. Defendant asserts no alternatively designed DPT vaccine existed at the time Hannah Bruesewitz received TRI-IMMUNOL® which was also approved for use on a child of Hannah's age.

As to Count II, Wyeth contends the failure-to-warn claim must also fail as a matter of law because Wyeth warned of the exact adverse event which allegedly befell Hannah Bruesewitz.

Further, Wyeth asserts that theories of strict liability are inapplicable to claims involving prescription drugs, requiring dismissal of Counts III and IV of the Complaint as a matter of Pennsylvania state law. Wyeth finally contends Plaintiffs have not met the burden of establishing facts sufficient to warrant a trial on the claim of a manufacturing defect because the evidence is insufficient to allow a jury to find the vaccine Hannah Bruesewitz received failed to meet its intended design specifications in any way.

2. Plaintiffs

Plaintiffs' view of Vaccine Act preemption arises from a fundamentally differing interpretation of the Act's plain meaning and congressional intent than espoused by Defendant. Plaintiffs first assert that a textual interpretation of the Act does not support preemption of all design defect claims. Plaintiffs contend that, by only preempting state tort law for "unavoidable"

harms, Congress left it to courts applying state law to determine this issue of avoidability on a case-by-case basis, and then adjudicate claims arising from avoidable harms; only if a court found that the harm suffered by a specific individual was “unavoidable,” would preemption apply. Plaintiffs point out that the Vaccine Act could have, but does not, explicitly bar claims for design defects. Plaintiffs contend that such a drastic reduction in the purview of state tort systems should not be inferred when Congress could have so easily made it clear.

According to Plaintiffs, while the Act was clearly meant to limit vaccine manufacturers’ exposure to liability, Congress never intended to preclude injured parties from pursuing claims in tort. In Plaintiffs’ view, Congress has encouraged vaccine manufacturers to continue producing vaccines by granting protection from lawsuits based on injuries caused by unavoidable side effects; however, Plaintiffs maintain that Congress also intended state tort systems to act partly as a goad to encourage further innovation and improvements of vaccines. Vaccine manufacturers continue to be liable for *avoidable* side effects; avoidability must be determined on a case-by-case basis. Plaintiffs argue that prior, factually similar cases were incorrectly decided. Specifically regarding Count II, Plaintiffs contend Wyeth has attempted to mischaracterize the warnings supplied with the vaccine as part of the vaccine’s design, thereby avoiding the fact that failure-to-warn claims are ordinarily not preempted under the Vaccine Act.

On the merits of their design defect claims, Plaintiffs argue that the existence of safer alternatives to TRI-IMMUNOL® rendered the design of that vaccine defective. In their Further Statement of Undisputed Facts, Plaintiffs aver Wyeth bought the license for an alternative, “non-cellular” DPT vaccine, TRI-SOLGEN, but never marketed the drug. (Pl’s Further Statement of Undisputed Facts ¶¶ 1-3, 7, 8.) Defendant does not dispute this fact, but contends it is irrelevant.

Plaintiffs urge against dismissal of Count II, arguing Wyeth is not entitled to the presumption of adequate warnings because Wyeth has not yet established that its product was unavoidably unsafe.

In support of their manufacturing defect claims at Counts I and IV Plaintiffs suggest the proper definition of a manufacturing defect compares the allegedly defectively manufactured product to a perfectly manufactured product of the same product line. According to Plaintiffs, this analysis establishes a manufacturing defect in that Wyeth knew a certain number of adverse reactions occurred in each lot of vaccine. Plaintiffs contend that Defendant's decisions about quality control are not a design defect, but rather reflect Defendant's willingness to allow a certain number of defectively manufactured vaccine lots be administered to patients. As such, Plaintiffs claim the evidence shows Hannah received a dose of vaccine from a lot associated with at least two deaths and more than 66 injuries (Pl's Further Statement of Undisputed Facts ¶ 4), and they have therefore established sufficient facts from which a jury could reasonably conclude she received vaccine from a defectively manufactured lot. In a final twist, Plaintiffs challenge Defendant's state-law defenses, contending the Vaccine Act preempts any state laws which limit the rights of vaccine recipients to sue for any reason not barred by the Act.

IV. Legal Standard

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). An issue is "genuine" if the evidence is such that a reasonable jury could return a verdict for the non-moving party. Anderson v. Liberty Lobby,

Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). A factual dispute is “material” if it might affect the outcome of the case under governing law. Id.

A party seeking summary judgment always bears the initial responsibility for informing the district court of the basis for its motion and identifying those portions of the record that it believes demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). Where the non-moving party bears the burden of proof on a particular issue at trial, the moving party’s initial burden can be met simply by “pointing out to the district court that there is an absence of evidence to support the non-moving party’s case.” Id. at 325. After the moving party has met its initial burden, “the adverse party’s response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial.” FED. R. CIV. P. 56(e). Summary judgment is appropriate if the non-moving party fails to rebut by making a factual showing “sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” Celotex, 477 U.S. at 322. Under Rule 56, the Court must view the evidence presented on the motion in the light most favorable to the opposing party. Anderson, 477 U.S. at 255.

V. Discussion

A. Vaccine Act

The legislative history of the Vaccine Act describes the creation of “a new system for compensating individuals who have been injured by vaccines routinely administered to children.” H.R. Rep. No. 99-908 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. The new system, the NVICP, includes a streamlined adjudication process in which the injured recipient of a vaccine

(or the injured party's legal representative) brings a claim in the United States Court of Federal Claims. The claimant receives compensation if it can be shown that the injured party (1) received a vaccine covered by the Act, (2) suffered injuries associated with that vaccine, and (3) it cannot be shown by a preponderance of the evidence that the injuries were not caused by the vaccine. 42 U.S.C. § 300aa-13.

The NVICP came about, in part, due to the inadequacy of state common law tort systems to provide either relief to injured children and their families, or predictable standards of liability to vaccine manufacturers. H.R. Rep. No. 99-908 at 7. On the one hand, claims brought against vaccine manufacturers by the parents of injured children required large amounts of time and money for an uncertain result. Id. at 6. On the other hand, manufacturers were also burdened by the time and expense of litigation. Although most cases ended favorably for the manufacturers, the extremely large sums returned by some juries, and the increased number of suits, meant that liability insurance was no longer affordable. Id. at 7. As a result many pharmaceutical manufacturers had left, or intended to leave, the childhood vaccine market. Id.

The NVICP is a streamlined, "no-fault" compensation scheme in which injured vaccine recipients recover damages without showing "causation of injury and without a demonstration that a manufacturer was negligent or that a vaccine was defective." Id. at 12. The House Committee Report anticipated the NVICP would divert "a significant number of potential plaintiffs from litigation" due to the system's speed, low transaction costs, no-fault nature, and the relative certainty and generosity of the system's rewards. Id. at 13. The Report noted that many people without any remedy under state tort laws would also be compensated by the NVICP.

Thus, the NVICP is meant to help maintain the national vaccine supply, both by ensuring compensation to injured children and their families, as well as by providing vaccine manufacturers with an affordable and predictable way of handling such compensation so as to allow them to continue to profitably make vaccines. Id.

In addition to creating this new compensation scheme, the Vaccine Act limits injured parties' remedies in tort. See 42 U.S.C. § 300aa-22; H.R. Rep. No. 99-908. Informed by the Restatement (Second) of Torts § 402A comment k,³ the Vaccine Act holds vaccine manufacturers immune from liability "if the injury or death resulted from side effects that were *unavoidable* even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1) (emphasis added).

The major legal issues before the Court relate to section 22 of the Vaccine Act: (1)

³ Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk. Restatement (Second) of Torts § 402A cmt. k (1965).

whether subsection 22(b)(1) presents a complete bar to design defect claims; (2) whether Plaintiffs have complained of a failure to warn that is not protected by the Act; and (3) whether Wyeth's defenses based in Pennsylvania state law are preempted by subsection 22(e). Section 22 of the Vaccine Act provides, in relevant part:

(a) General Rule. Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings.

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after Oct. 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 301 *et seq.*] and section 262 of this title (including regulations under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or (B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings. No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after Oct. 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

...

(e) Preemption. No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle [42 U.S.C. §§ 300aa-10 *et seq.*].

42 U.S.C § 300aa-22.

B. Design Defect Claims Under the Vaccine Act⁴

1. Prior Rulings Upholding Vaccine Act Preemption

To date, analogous cases which required a ruling as to whether the Vaccine Act bars claims for design defects have been decided by two intermediate state appellate courts and two federal district courts. All but one have held the Vaccine Act preempts design defect claims, including Judge Stengel in this District. The reasoning in each of the three cases is very similar. The first federal ruling is Blackmon v. American Home Products Corp., 328 F. Supp.2d 659 (S.D. Tex. 2004). The court granted defendants' motion for partial summary judgment, holding the Vaccine Act entirely bars injured vaccine recipients from claiming a design defect under state tort law. Id. at 666. The court only partially granted summary judgment of plaintiffs' failure-to-warn claim. See id. at 666-67.

In Blackmon, parents sued on behalf of their child who suffered neurological disorders as a result of the mercury preservative (thimerosal) used in the vial containing a vaccine administered to the child. The parents' theory of liability was that the vaccine was not unavoidably unsafe because thimerosal was only used in multi-dose vials. If the vaccine manufacturers had provided single-dose vials, no preservative would have been necessary, and

⁴The Vaccine Act limits a manufacturer's liability for design defects regardless of the cause of action. Therefore, the analysis below applies equally well to Plaintiffs' negligence claim at Count I and their strict liability design defect claim at Count III. Sykes v. Glaxo-Smithkline, 484 F. Supp. 2d 289, 303 (E.D. Pa. 2007) ("The text of the Vaccine Act that limits a manufacturer's liability is not directed toward any particular cause of action."); Blackmon v. American Home Products Corp., 328 F. Supp. 2d 659, 666 (S.D. Tex. 2004) ("The phrase 'a civil action for damages' encompasses products liability claims based on negligence as well as those based on strict liability. While comment k is restricted to strict liability claims, § 22(b) is not.")

their child would not have suffered any injuries. 328 F. Supp.2d at 663.

Defendants argued § 22(b)(1) totally preempts state law, constituting a complete bar to design defect claims for any vaccine approved by the FDA. The plaintiffs countered that whether the drug was unavoidably unsafe should be determined on a case-by-case basis under state law, requiring a jury to determine the merits of their alternate design theory, the single-dose vial that contains no preservative, in spite of the FDA's approval of defendants' vaccine. Id.

Relying on the legislative history, the court concluded the policy of the Vaccine Act is to protect the national vaccine supply by protecting manufacturers from the potential inconsistencies of the 50-state tort system, while still providing parents with a remedy should their child be harmed by a vaccine. See id. at 665 ("The last passage [of the legislative history] indicates rather clearly the Committee's intent to relegate design defect claims to the compensation system, provided that the injury-producing vaccine was manufactured and distributed according to applicable federal standards.")

The court compared § 22(b)(1) to the Restatement (Second) of Torts § 402A cmt. k, finding that Congress intended to incorporate the comment's liability principles into the Vaccine Act. Id. at 664. The court's interpretation of comment k led it to conclude that, without a complete bar to design defect claims, § 22(b)(1) would be stripped of all meaning. Id. at 665. In the court's view, defects that are "truly unavoidable in the broad, literal sense" would render claims meritless to begin with, thus leaving no need for congressional protection. See id. In the court's view, allowing a case-by-case determination of unavoidability would undercut not only the protections the Vaccine Act provides vaccine manufacturers, but also the broader, "comprehensive regulatory scheme, administered by the FDA, to control the design and

distribution of prescription drugs, including vaccines.” Id. at 665.

Finally, the court concluded the Vaccine Act makes no distinction between theories of liability based on strict liability or negligence. While acknowledging that comment k only applies to strict liability in the Restatement, the court noted that § 22(b)(1) granted immunity in “a civil action for damages,” thus encompassing both theories of liability. Id. at 666.

Since Blackmon, Judge Stengel of this Court made a similar ruling in Sykes v. GlaxoSmithKline, 484 F. Supp. 2d 289 (E.D. Pa. 2007). In Sykes the plaintiffs asserted strict products liability and negligence against three pharmaceutical companies for alleged injuries to the minor plaintiff, Wesley Sykes, claiming, in part, that defendants’ products were defectively designed and that safer alternatives existed at the time the drugs were administered. Id. at 294. As in Blackmon, the plaintiffs alleged injuries to the minor plaintiff resulted from a negative reaction to the mercury preservative thimerosal used in the vaccines administered to him. Id.

Upon the defendants’ motion to dismiss, Judge Stengel held, “the plaintiffs’ defective design claims against [the vaccine manufacturer defendants], based on a strict liability theory, are barred.” Id. at 301. The court, largely adopting the reasoning in Blackmon, based its ruling on four basic conclusions: (1) the purpose of the Vaccine Act to protect vaccine manufacturers from the unpredictability and expense of the tort system would be thwarted by allowing juries to decide design defect claims by evaluating whether a vaccine was unavoidably unsafe on a case-by-case basis; (2) through the Vaccine Act, Congress delegated to the Department of Health and Human Services, rather than the jury system, the role of assuring improvements in the quality, effectiveness, and safety of vaccines; (3) the Vaccine Act protects manufacturers from design defect claims in particular; and (4) comment k supports the understanding that the liability of

vaccine manufacturers is limited to claims that the vaccine deviated from its FDA-approved design. Sykes, 484 F. Supp. 2d at 301-03. The court further found Vaccine Act preemption applies to claims for both negligence and strict liability. Id. at 303.

Intermediate appellate courts in two states have disagreed on the preemption issue. Upholding a trial court's grant of summary judgment in favor of vaccine manufacturers in Militrano v. Lederle Labs., 810 N.Y.S.2d 506 (N.Y. App. Div. 2006),⁵ the court held, "Congress' intent in enacting the prohibition on civil actions by the Vaccine Act was to adopt by reference Restatement (Second) of Torts § 402A, comment k." Id. at 508. While recognizing that the discussion of comment k in an early portion of the Committee Report leaves open the possibility of design defect claims, the court found a later section foreclosed that option. Id. The later section states,

Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.

H.R. Rep. No. 99-908 at 508. Noting "[p]reemption is a question of Congressional intent," Militrano, 810 N.Y.S.2d at 477 (citing California Fed. Sav. & Loan Assn. v. Guerra, 479 U.S. 272, 280 (1987)), the court found Congress clearly intended to preclude all design defect claims with respect to vaccines covered by the Vaccine Act. Id.

2. The Ruling Rejecting Preemption⁶

⁵ The trial court's decision in Militrano v. Lederle Labs., 769 N.Y.S.2d 839 (N.Y. Sup. Ct. 2003), is the first ruling by any court on Vaccine Act preemption of design defect claims.

⁶Plaintiffs point to Mazur v. Merck & Co., 742 F. Supp. 239 (E.D. Pa. 1990), as precedent from this District rejecting preemption. In Mazur, Judge Ditter found, "Pennsylvania

In the trial court opinion in Ferrari v. Amer. Home Products Corp., No. 02-VS-031404-F, slip op., 7-8 (Sup. Ct. Fulton Co. Nov. 30, 2005), it was the *plaintiffs* who argued Congress had simply incorporated comment k into § 22(b)(1). Although the court disagreed with the plaintiffs' contention on this point, it considered its ruling in accord with Blackmon. Id. at 8. The court reasoned that plaintiffs' reading of comment k and the Vaccine Act would be correct if § 22(b)(1) exempted injuries resulting from "side effects that were unavoidable," but since the exemption is for "side effects that were *unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings*," plaintiffs' interpretation did not account for all the elements of the statute. Id. (emphasis in original). The court found, "By its express terms, the statute immunizes vaccine manufacturers from liability for side effects that inevitably occur even though a vaccine is properly prepared in every respect according to its approved design specifications and is properly labeled," id., thereby adopting the same understanding as in Blackmon that FDA approval defines what vaccines are unavoidably unsafe.

The Court of Appeals of Georgia overturned the above ruling in a unanimous decision. Ferrari v. American Home Products Corp., No. A07A0306, 2007 WL1933129 (Ga. Ct. App. July 5, 2007). The court based its opinion on an admittedly novel application of Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005), to § 22(b), acknowledging that none of the previous courts to address this issue had considered Bates. 2007 WL 1933129, at *3. According to the Court of Appeals of Georgia, if a preemption statute is ambiguous, Bates requires a court to

tort law is not preempted by federal regulation of vaccine manufacture, distribution, and labeling, in general." 742 F. Supp. at 248. Wyeth has conceded that manufacturing claims and certain failure-to-warn claims are not preempted by the Vaccine Act. Mazur is inapposite to the context in which Plaintiffs cite it, as it does not address design defect claims.

adopt the reading that disfavors preemption. *Id.* at *4. The Georgia court noted its accord with *Sykes*⁷ and *Militrano*⁸ in that § 22(b) is ambiguous as to whether injuries are, “‘unavoidable’ and subject to preemption if the vaccine was properly prepared and accompanied by proper directions and warnings . . . [or whether] design defect claims are preempted only if the side-effects are determined to be unavoidable on a case-by-case basis.” *Ferrari*, 2007 WL 1933129, at *4.

Although the court agreed with all the previous courts’ findings as to congressional intent, it held that *Bates* required it to apply the interpretation disfavoring preemption, notwithstanding that intent. *Id.* (“We recognize that this result is anomalous given the clear legislative history to the contrary, but we are constrained to follow the Supreme Court’s explicit guidance in *Bates*.”) The Georgia court therefore remanded the case for proceedings as to whether the vaccine was unavoidably unsafe.

a. *Bates* does not alter the preemption analysis of the Vaccine Act

Bates is a recent Supreme Court case addressing the scope of the preemption provision in the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. § 136 *et seq.*⁹ Plaintiffs brought claims against the defendant, a pesticide manufacturer, when their peanut harvest was damaged by use of the defendant’s pesticide in alkaline soil despite the pesticide label claiming its appropriateness for use anywhere peanuts are grown. *Bates*, 544 U.S. at 435-36. The Fifth Circuit upheld the district court’s finding of preemption, reasoning that the

⁷See 484 F. Supp. 2d at 308-309.

⁸See 769 N.Y.S.2d at 843-844.

⁹The preemption provision states, “[States] shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.” 7 U.S.C. § 136v(b).

plaintiffs' tort claims, if successful, would induce the defendant to change its label. Id. at 436. In overruling, the Supreme Court first noted, "FIFRA [is] not a sufficiently comprehensive statute to justify an inference that Congress had occupied the field to the exclusion of the States." Id. at 441-42 (internal quotations omitted). Next, it held, "Nothing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense." Id. at 442. Finally, the Court found the ban on states imposing a "requirement" did not preempt the creation of an "inducement." Id. at 445. The plaintiffs' claims were for defective design, as well as violation of an express warranty, rather than a defective warning label. Id. at 444. The Court reasoned the duties imposed by such common law rules might induce the pesticide manufacturer to change its labeling; however, an adverse jury verdict would not *require* the manufacturer to change. Id. at 445. As such, design defect claims at common law are not preempted by the express language of the FIFRA preemption provision. The Supreme Court found, however, the plaintiffs' alleged fraud and failure-to-warn claims to be preempted, since those claims were "premised on common-law rules that qualify as 'requirements for labeling or packaging.'" Id. at 446. In this way, the Supreme Court adopted a "parallel requirements" reading of the FIFRA preemption provision. Id. at 447. The Court explained, FIFRA "does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*." Id. at 448 (emphasis in original).

Notwithstanding the Georgia Court of Appeal's application of Bates to the Vaccine Act, this Court rejects that application. Simply because the Bates Court, when faced with two plausible alternative readings of the FIFRA preemption statute, opted for the reading that disfavors preemption, the Ferrari appeals court applied a similar reading to § 22(b). Ferrari, 2007

WL 1933129, at *4. However, Bates does not require a court to automatically accept a plausible interpretation of a statute which disfavors preemption. Even assuming, *arguendo*, that Plaintiffs have offered a plausible alternate reading of § 22(b), the Ferrari holding takes only one part of the Bates ruling out of its context, and gives it broader scope than is appropriate.

The Ferrari court agreed with Sykes, Blackmon, and Militrano that the legislative history of the Vaccine Act clearly demonstrates congressional intent to completely preempt design defect claims, and also considered the Bates rule disfavoring preemption as “outcome determinative,” irrespective of congressional intent. Ferrari, 2007 WL 1933129, at *5. However, Bates itself relies on the congressional intent behind FIFRA when applying the rule. 544 U.S. at 449 (“The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption.”) The Court continued, “If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.” Id.

Thus, even though there is a “basic presumption against pre-emption,” id., a court must look to whether that presumption accords with Congress’ intent in enacting a specific law. The Third Circuit, discussing implied conflict preemption, very recently held, “[t]his question is basically one of congressional intent. Did Congress, in enacting the Federal Statute, intend to exercise its constitutionally delegated authority to set aside the laws of a State? If so, the Supremacy Clause requires courts to follow the federal, not state, law.” Pennsylvania Employees Benefits Trust Fund v. Zeneca, Inc., No. 05-5340, slip op. at 20 (3d Cir. Aug. 17, 2007) (*quoting* Barnett Bank of Marion County, N.A. v. Nelson, 517 U.S. 25, 30 (1996)).

Importantly, as previously noted, the Bates Court held FIFRA not to be “a comprehensive

statute to justify an inference that Congress had occupied the field to the exclusion of the States.” Id. at 441-42. In the case of FIFRA, the Supreme Court found the long history of tort litigation against pesticide manufacturers “emphasizes the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items.” Bates, 544 U.S. at 450 (*citing* Wisconsin Public Intervenor v. Mortier, 501 U.S. 597, 613 (1991)). As another court has recently noted, the Bates decision “was moored tightly to the specific preemption clause at issue.” Mills, M.D., v. Giant of Maryland, LLC, 441 F. Supp. 2d 104, 107 (D.D.C. 2006) (dismissing as preempted claims against milk and milk-product marketers for failing to warn of the risks of lactose intolerance). “Bates merely underscores the need to pay close attention to the scope of the [federal statute’s] preemption clause and assists the court in framing the questions to be addressed.” Id. at 107. Bates does not decide the question whether the Vaccine Act preempts all design defect claims, or whether there must be a case-by-case determination as to whether a vaccine is unavoidably unsafe.

3. The Vaccine Act preempts design defect claims

This case does not materially deviate from the facts in the precedents cited above, as regards Plaintiffs’ design defect claims. In all four vaccine design defect cases cited above, the plaintiffs asserted that a vaccine was defectively designed because the defendants knew of the risk of adverse reactions. In all four cases, the plaintiffs posited a theoretical alternative design which would have resulted in a safer vaccine. Plaintiffs here make the same arguments.¹⁰

¹⁰Indeed, while the plaintiffs in Blackmon, Ferrari, and Sykes complained of the use of the mercury-based preservative, thimerosal, the Militrano plaintiffs advanced precisely the argument brought here; namely, that the defendant should have sought earlier approval for a safer alternative. See Militrano, 769 N.Y.S.2d at 847.

Comment k, by offering the example of the rabies vaccine, presents a situation in which a manufacturer should be immune from liability because administering the vaccine is always preferable to not administering it, despite the risks inherent in the vaccine. In this example, the individual has only two choices: the individual must either accept the risks associated with rabies, or the risks associated with its treatment. This dichotomy explicitly assumes that there is no better, alternative rabies vaccine which avoids the risk inherent in the first one. See Restatement (Second) of Torts § 402A cmt. k (“There are some products which, *in the present state of human knowledge*, are quite incapable of being made safe for their intended and ordinary use.” (emphasis added)) Comment k, therefore, suggests that the question of whether a particular vaccine is unavoidably unsafe--and therefore subject to the immunity from suit posited by comment k--is a question of fact for a jury to determine. That is, the trier of fact must decide whether the challenged vaccine is the only design available, “in the present state of human knowledge.”

Sykes’ four conclusions, *supra* Part V.B.1, provide the standard by which this Court finds design defect preemption under the Vaccine Act . Using this framework, the following conclusions may be drawn: First, allowing case-by-case inquiries into whether a particular vaccine is unavoidably unsafe would do nothing to protect vaccine manufacturers from suit from design defects, since such an inquiry would require a finder of fact to consider the manufacturer’s design against a purported safer alternative.

Second, the Vaccine Act provides for the NVICP to, “promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines.” 42 U.S.C. §

300aa-27(a)(1). That the same program which provides no-fault remedies to injured vaccine recipients also promotes the discovery of safer alternative designs, suggests Congress intended to provide an umbrella under which manufacturers would improve the safety of their products while remaining immune from design defect claims made possible by the successful innovation of safer alternative designs.

Third, the Vaccine Court's no-fault compensation scheme reflects the other side of the balance Congress struck between the policy of widespread distribution of childhood vaccines and the need to compensate those injured effecting that policy. See H.R. Rep. No. 99-908 at 13; *supra* Part V.A.

Finally, whereas Sykes understands the Vaccine Act to "mirror[]" this established area of tort law for unreasonably unsafe products," 484 F. Supp. 2d at 303, this Court concludes that § 22(b) is broader than comment k, so that the Vaccine Act preempts state law determinations of whether a vaccine is unavoidably unsafe, and therefore entitled to comment k immunity. In approving the design of a vaccine, the FDA considers the safety and efficacy of that vaccine. See 42 U.S.C. § 262(a) ("The Secretary [Health and Human Services] shall approve a biologics license application (i) on the basis of a demonstration that (I) the biological product that is the subject of the application is safe, pure, and potent."); see also Blackmon, 328 F. Supp. 2d at 665. An FDA-approved vaccine design includes the side-effects of that vaccine, and is therefore, by statutory definition, the unavoidably unsafe product subject to comment k immunity. As such, § 22(b) of the Vaccine Act represents part of a comprehensive statutory scheme which preempts all design defect claims brought under state tort law. Applying the "parallel requirements" holding of Bates, the Court concludes Congress did not intend to allow a case-by-case determination as to

whether a vaccine is unavoidably unsafe. Doing otherwise would allow state common law to impose additional requirements on vaccine manufacturers wishing to avoid liability, rather than merely providing additional remedies for violating federal law. Compare Bates, 544 U.S. at 448 (“[FIFRA] does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.”) with 42 U.S.C. § 300aa-22(b)(1) (“No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine related injury or death . . . , if the injury or death resulted from side effects that were unavoidable . . .”).

To further this point, the Court will address Rohrbough v. Wyeth Laboratories, Inc., 719 F. Supp. 470 (D.W. Va. 1989), in which the court found that a vaccine manufacturer may only avail itself of comment k immunity after “first demonstrat[ing] that its vaccine was ‘unavoidably unsafe,’” id. at 477, and upon which Plaintiffs rely for their argument against design defect preemption. The court reached its conclusion based on West Virginia’s adoption of comment k. The court denied the defendant manufacturer’s summary judgment motion because factual issues existed as to the question of unavoidability. What Plaintiffs fail to account for, however, is that Rohrbough does not implicate the Vaccine Act because the Vaccine Act was not operative. Although Rohrbough was decided three years after the passage of the Act, the facts of the case show that the vaccine in question was administered in 1983 and 1984, before Congress enacted the Vaccine Act. See id. at 472. Section 22 of the Vaccine Act only applies to vaccines administered after October 1, 1988. 42 U.S.C. § 300aa-22(b)(1). As such, Rohrbough represents precisely the action against which § 22 is meant to protect vaccine manufacturers, not an argument in favor of Plaintiffs’ design defect claims.

Counts I and III are claims for design defects preempted by the Vaccine Act, and will be

dismissed with prejudice.¹¹

C. Failure-to-Warn Claims

The Vaccine Act clearly bars failure-to-warn claims based on a failure to directly warn the injured party or the injured party's legal representatives. 42 U.S.C. § 300aa-22(c). The Amended Complaint, however, alleges Defendant withheld specific information from doctors about particularly dangerous batches of the vaccine, including Hannah Bruesewitz' own doctor. (Am. Compl. ¶ 35.) As the court found in Blackmon, allegations of a failure to warn "doctors and medical intermediaries" are not subject to the prohibition of § 22(c). 328 F. Supp. 2d at 666. Even so, the Vaccine Act also grants a vaccine manufacturer the presumption of a proper warning if the manufacturer "shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act." 42 U.S.C. § 300aa-22(b)(2). "The Vaccine Act imposes a burden of production on the manufacturer to show material compliance with FDA regulations." Blackmon, 328 F. Supp. 2d at 667.

Once the manufacturer meets that burden, however, the burden shifts to the plaintiff to

¹¹Plaintiffs' claim that they have exhausted their administrative remedies is beside the point. The Vaccine Act does not provide for district courts to sit in review of the Vaccine Court, as Plaintiffs argument would suggest. Indeed, Plaintiffs only allege state law violations in tort, and this Court has jurisdiction solely due to the diversity of the parties, and not because of a federal question. See This Court's Memorandum and Order dated March 27, 2006 (Doc. No. 13), 2007 WL 782437. The Vaccine Act grants exclusive jurisdiction over NVICP claims to the Vaccine Court. See 42 U.S.C. § 300aa-12(a). Appeals go to the Federal Circuit. 42 U.S.C. § 300aa-12(f). Only after the Vaccine Court has issued a ruling, or has failed to do so, does the Act allow claimants to take their case beyond the NVICP. However, civil actions in tort are manifestly different from proceedings before the Vaccine Court. As discussed, *supra* Part V.A., the Vaccine Court is a no-fault compensation scheme that requires no showing of negligence, or even of causation. H.R. Rep. No. 99-908 at 12. That standard is far different from the traditional tort claims which must be brought after a party rejects the findings of the Vaccine Court, alleging negligence or strict liability, as are discussed below.

present evidence that the manufacturer engaged in fraud or wrongful withholding of information from the Secretary of Health and Human Services either during or after the approval process, or by “clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with [the laws and regulations regarding drug approval proceedings].” See 42 U.S.C. §§ 300aa-22(b)(2)(A) and (B).

Defendant first argues that Plaintiffs’ failure-to-warn claim merely repackages their design defect claims under a different title. The Court rejects Defendant’s interpretation of Plaintiffs’ failure-to-warn claim because Plaintiffs have alleged facts which fit squarely into the two exceptions to the failure-to-warn immunity provided in § 22(b)(2). The issues on summary judgment therefore become whether Wyeth has made a showing of evidence to avail itself of the presumption of proper warnings, and if so whether Plaintiffs can mount facts sufficient to rebut the presumption.

1. Defendant are entitled to the presumption of proper warning

Defendant relies on the Declaration of Dennis J. Foley, Ph.D., and the exhibits attached thereto to demonstrate that throughout its history of use, from 1943 until it was taken from the market in 1998, TRI-IMMUNOL® has been licensed by the appropriate federal agency. Moreover, the FDA approved the package insert containing the warning provided along with the vaccine administered to Hannah Bruesewitz. Most importantly, Plaintiffs do not dispute that the warning provided by Defendant complied with the relevant federal laws and regulations. Defendant is therefore entitled to the presumption that TRI-IMMUNOL® was “accompanied by proper directions and warnings.” 42 U.S.C. § 300aa-22(b)(2).

2. Plaintiffs have failed to rebut the presumption

The Amended Complaint does not allege fraud or wrongful withholding of information from the Secretary of Health and Human Services. Plaintiffs have omitted that allegation in the original Complaint in filing the Amended Complaint. In any case, Fed. R. Civ. P. 9(b) requires Plaintiffs plead fraud with particularity rather than supplying a mere “recitation of the Vaccine Act language.” Sykes, 484 F. Supp. 2d at 306. Plaintiffs must therefore show, “by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with [the laws and regulations regarding drug approval proceedings].” 42 U.S.C. §§ 300aa-22(b)(2)(B). In support of their failure-to-warn claim, Plaintiffs only cite the affidavit of Donald H. Marks, M.D., Ph.D., and the exhibits attached thereto. Plaintiffs have identified which lot produced the dose of TRI-IMMUNOL® administered to Hannah Bruesewitz, as well as the Vaccine Adverse Event Reporting System (“VAERS”)¹² report confirming deaths and other adverse events associated with that lot. (Marks Aff. Ex. 15.) Plaintiffs also offer the deposition testimony of Hannah Bruesewitz’ doctor, Jane M. Breck, M.D. to establish that, had she known the vaccine to be administered to Hannah had come from a lot associated with at least two deaths and more than 30 injuries, she would not have administered that particular dose of vaccine.¹³

According to Dr. Marks, such a batch, associated with deaths and adverse reactions, is

¹²VAERS is a database created, pursuant to the Vaccine Act, by the FDA and the Centers for Disease Control and Prevention to receive reports about adverse events which may be associated with vaccines. “The primary purpose for maintain the database is to serve as an early warning system for adverse events not detected curing pre-market testing.” (Marks Aff. Ex. 14., “Important Information from the FDA about the Vaccine Adverse Event Reporting System”.)

¹³These two documents, the VAERS report, and the deposition of Dr. Breck, substantiate paragraphs 4-6 of Plaintiffs’ Further Statement of Undisputed Facts.

sometimes referred to as a “Hot lot.” Dr. Marks relies on a memorandum from the Department of Health and Human Services to define a “Hot lot” as a “fill lot[] that exceeded a threshold of \geq 2 deaths or \geq 2 convulsions or \geq 10 total reports.” (Marks Aff. Ex. 8.) The memorandum, however, actually refers to such a lot as a “*potential* hot fill lot[]” and goes on to explain that the total number of doses distributed must be known in order to account for a potential reporting bias. (*Id.*) (emphasis added). In other words, according to the evidence produced by the Plaintiffs themselves, a “Hot lot” is not defined by the total number of adverse incidents, but rather by the rate at which those incidents occurred. Plaintiffs have produced no evidence from which a trier of fact could infer that the dose in question originated in a lot of vaccine associated with a disproportionate number of adverse health effects. Indeed, Plaintiffs provide evidence that Wyeth and its relevant corporate predecessors were aware that certain lots of TRI-IMMUNOL® were associated with higher rates of adverse events, and that Wyeth took steps to withdraw those lots from distribution. (Marks Aff. ¶¶ 6-7 Ex. 2, 3.) Therefore, Plaintiffs have failed to establish that the dose of vaccine administered to Hannah Bruesewitz originated in a “Hot lot.”

Under Pennsylvania law, whether warning labels on prescription drugs are adequate is a matter for the jury to decide. *Incollingo v. Ewing*, 444 Pa. 263, 289-90 (1971) (“We think that whether or not the warnings on the cartons, labels and literature of [the defendant drug manufacturer] in use in the relevant years were adequate, and whether or not the printed words of warning were in effect cancelled out and rendered meaningless . . . , were questions properly for the jury.”) In the instant case, however, Congress has established a presumption of adequate warning to which this Court has found Wyeth is entitled. Plaintiffs have not pointed to any evidence showing the lot from which Hannah Bruesewitz’ dose came was a “Hot lot” or that

Wyeth acted in a way to suggest it believed it was a “Hot lot.” There has been no showing by Plaintiffs that the vaccine dose in question was materially different from any other vaccine dose for which the warning had been approved. Plaintiffs simply have no evidence to support their contention that Hannah Bruesewitz received a dose of vaccine originating from a “Hot lot.” Therefore, Plaintiffs have failed to present “clear and convincing” evidence that Defendant failed to exercise due care. The Court will grant summary judgment in favor of Defendant as to Count II of the Amended Complaint.

D. Manufacturing Defect

Defective manufacture provides a cause of action for strict liability in Pennsylvania. See Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 748 (E.D. Pa. 2007) (Robreno, J.) (*citing Phillips v. A-Best Prods. Co.*, 542 Pa. 124 (1995)). Under Pennsylvania law, a plaintiff alleging a product manufacturing defect based on a theory of strict liability must show that (1) the product was defective; (2) the defect was the proximate cause of the plaintiff’s injuries; and (3) the defect causing the injury existed when the product left the seller’s hand. Id. at 749 (*citing Pavlik v. Lane Limited/Tobacco Exporters Int’l*, 135 F.3d 876, 881 (3d Cir. 1998)). “A product will be deemed defective only if it ‘left the supplier’s control lacking any element necessary to make it safe for its intended use or possessing any feature that renders it unsafe for the intended use.’” Commonwealth Dept. of General Services v. U.S. Mineral Products Co., 2007 WL 1892076, * 5 (Pa. Cmmw. Ct. July 3, 2007) (*quoting Azzarello v. Black Bros. Co., Inc.*, 480 Pa. 547, 559 (1978)).

Wyeth concedes the Vaccine Act does not preempt claims for manufacturing defects. Instead, Wyeth argues Plaintiffs’ manufacturing defect claim must fail because there is no

dispute that the dose administered to Hannah Bruesewitz was made within design specifications, and therefore was not defective.¹⁴ Plaintiffs first counter that they allege a classic manufacturing defect claim, asserting that the dose administered to Hannah Bruesewitz had “an inappropriate balance between neuro-toxins and endo-toxins in the pertussis vaccine.” (Am. Compl. ¶ 39.) Setting aside the legal consequences if such a claim were true (which Wyeth disputes), Plaintiffs have offered absolutely no evidence to support this allegation, as is their burden to do in response to Defendant’s summary judgment motion. Meanwhile, Wyeth provides the Declaration by Mary B. Ritchey, Ph.D., in which she states, “The pertussis bacterium does not contain a recognized ‘neuro-toxin’ component. Indeed, I do not understand what part of the pertussis vaccine plaintiffs refer to when they allege that ‘neuro-toxins’ were not balanced with endotoxins in TRI-IMMUNOL®. . . . To my knowledge it has never been proven that whole-cell pertussis vaccine has a neuro-toxic effect.” (Ritchey Decl. ¶ 9.) Defendant has therefore offered evidence that the specific manufacturing defect alleged by Plaintiffs, an imbalance of “neuro-toxins” and “endo-toxins,” did not exist. Plaintiffs have offered no evidence sufficient to raise a genuine issue as to this fact.

Even without direct evidence of a manufacturing defect, one may be inferred where there is circumstantial evidence of a malfunction. To that end, Plaintiffs hold up the phenomenon of the “Hot lot” as circumstantial evidence of a manufacturing defect. Under Pennsylvania law, Plaintiffs’ argument is known as the “malfunction theory.”

¹⁴As with Plaintiffs’ failure-to-warn claim, Wyeth first characterizes the allegations in Count IV as merely another iteration of the original design defect claim. The Court rejects this argument because Plaintiffs clearly allege that the vaccine administered to Hannah Bruesewitz differed materially from the intended design in that the lot from which that dose originated was allegedly more prone to adverse reactions than intended by the design. (See Am. Compl. ¶ 37.)

The malfunction theory permits a plaintiff to prove a defect in a product with evidence of the occurrence of a malfunction and with evidence eliminating abnormal use or reasonable, secondary causes for the malfunction. The plaintiff is relieved from demonstrating precisely the defect yet it permits the trier-of-fact to infer one existed from evidence of the malfunction, of the absence of abnormal use and of the absence of reasonable secondary causes.

Barnish v. KWI Bldg. Co., 916 A.2d 642, 646 (Pa. Super. Ct. 2007).

Pennsylvania precedent is devoid of cases applying the malfunction theory to the allegedly defective manufacture of vaccines or other prescription medical products. The general rule, however, is “[t]he questions when and where a defect originated should be left to the finder of fact so long as reasonable and well balanced minds (could) be satisfied from the evidence adduced that the defective condition existed when the [product] was delivered.” *Id.* (quoting Kuisis v. Baldwin-Lima-Hamilton Corp., 457 Pa. 321 (1974)). Plaintiffs offer evidence that when a “Hot lot” is discovered, the manufacturer changes the batch rather than producing more lots of vaccine from that batch. (Marks Aff. ¶¶ 6, 7 Ex. 2, 3.) If the production process for a DPT vaccine includes the removal from production of batches which are less safe than intended, an inference must be made in favor of Plaintiffs at the summary judgment stage that any such batches are defectively manufactured. *See Barnish*, 916 A.2d at 647.

However, the first prong of a manufacturing defect claim still requires the plaintiff to prove the product was defective. “Even though ‘proof of a specific defect is not essential to establish liability under [the malfunction] theory, the plaintiff cannot depend upon conjecture or guesswork.’” *Barnish*, 916 A.2d at 646 (quoting Woodin v. J.C. Penny Co., Inc., 629 A.2d 974, 976 (Pa. Super. Ct. 1993)). As discussed above, *supra* Part V.C., Plaintiffs have failed to offer evidence that the lot from which Hannah Bruesewitz’ dose of vaccine derived was a “Hot lot.”

As such, they have raised no genuine issue of material fact for trial as to whether the vaccine was defective, even under the malfunction theory.

Moreover, even if Plaintiffs had established that the vaccine was defective in this case, Plaintiffs have absolutely no evidence to satisfy the second prong of the test to determine liability for a manufacturing defect. That is, Plaintiffs cannot show “the defect was the proximate cause of the plaintiff’s injuries.” Soufflas, 474 F. Supp. 2d at 749. In Barnish, from which the definition of the malfunction theory is quoted, the defendant did not dispute that the alleged manufacturing defect was the proximate cause of the plaintiffs’ injuries. 916 A.2d at 644. In the instant case, Wyeth specifically denies the DPT vaccine caused any injury to Hannah Bruesewitz. Plaintiffs’ only evidence there was anything wrong with the particular vaccine lot from which Hannah Bruesewitz’ dose came is the VAERS report for that lot number. (See Marks Aff. ¶ 24 Ex. 15.) However, Plaintiffs have no evidence to support the proposition that the specific lot caused *any* of those adverse reactions, let alone the specific reaction suffered by Hannah Bruesewitz. Indeed, Plaintiffs’ own evidence negates the possibility that one may draw an inference from a VAERS report that the vaccine caused the reaction:

The report of an adverse event to VAERS is not a documentation that a vaccine caused the event. . . . Some infants will by coincidence experience such an event shortly after a vaccination. In such situations, the event may be caused by an infection, congenital abnormality, injury, or some other provocation. Because of such coincidences, it is usually not possible to be sure whether a particular adverse even resulted from a concurrent condition or from vaccination, even when it occurred soon afterward. Therefore, doctors and other vaccine providers are encouraged to report adverse events, whether or not they believe that the vaccination was the cause. Since it is difficult to distinguish a coincidental event from one truly caused by a vaccine, the VAERS database will contain events of both types.

(“Important VAERS Information” Marks Aff. Ex. 14.)

Accordingly, in the absence of any evidence that the dose of Defendant's vaccine administered to Hannah Bruesewitz was defective, or that it was the proximate cause of Plaintiff's injuries, summary judgment will be granted in favor of Defendant as to Count IV.¹⁵

VI. Conclusion

Counts I and III allege design defects, and are therefore preempted by the Vaccine Act. Counts II and IV are not preempted; however, Plaintiff has failed to produce evidence raising issues of material fact. Accordingly, Defendant's Motions for Summary Judgment will be granted as to all Counts. An appropriate Order follows.

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¹⁵Wyeth alternatively argues that Pennsylvania state law does not allow for a finding of strict liability for design defect or manufacturing defects in this case. Plaintiffs counter that the Vaccine Act preempts any bar to their claim. Pennsylvania has adopted Section 402A of the Restatement (Second) of Torts. Mazur v. Merck & Co., 964 F.2d 1348 (3d Cir. 1992). Therefore, Pennsylvania also provides immunity to the manufacturers of prescription drugs pursuant to comment k. See Hahn v. Richter, 673 A.2d 888, 891 (1996) ("the manufacturer's negligence, is the only recognized basis of liability.") However, not only does the Vaccine Act preempt state law allowing claims arising out of defectively designed vaccines, it also explicitly prohibits states from "establish[ing] or enforc[ing] a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle." 42 U.S.C. § 300aa-22(e). The Vaccine Act clearly permits manufacturing defect claims under § 22(b)(1), without reference to the theory of liability. Therefore, strict liability claims for manufacturing defect are not barred by the Vaccine Act. As such, the preemption provision in § 22(e) applies, and Pennsylvania's bar to strict liability claims for manufacturing defects, enunciated in Hahn, is preempted. As the Court will grant summary judgment as to Count III based on Vaccine Act preemption and Count IV on the merits, preemption of the Hahn rule does not impact the outcome of this case.

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

FILED

10/24/07

MAICHAEL M. BAYLSON, Clerk

BRUESEWITZ, et al.,

Plaintiffs,

v.

WYETH, INC.,

Defendant.

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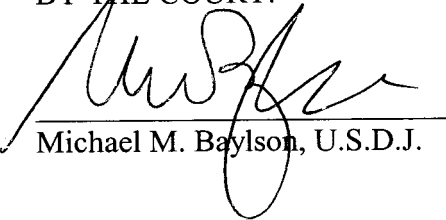
Civil Action

NO. 05-5994

ORDER

AND NOW, this ____ day of August 2007, upon consideration of Defendant's Motions for Summary Judgment, and all the Responses and Replies thereto, it is hereby ORDERED that Defendant's Motions to for Summary Judgment (Docs. No. 22, 73, 88) are GRANTED. Judgment is entered in favor of Defendant and against Plaintiffs. The Clerk shall close this case.

BY THE COURT:



Michael M. Baylson, U.S.D.J.